

USSN: 09/205,251
Atty Dkt: DURE-021
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REMARKS

Status of the Claims

Claims 1-25, 27, 30-53, 61-65, 69, and 79 are cancelled. Claims 26, 28, 29, 54-60, 66-68, 70-78, and 80-82 are pending in this application.

The Objection under 37 C.F.R. §1.83(a)

Applicants note that the objection under 37 C.F.R. §1.83(a) has been maintained. Applicants traverse the objection for the reasons of record (reproduced herein), and point out that the requirements of the objection have been met. Reconsideration and withdrawal of the objection to the drawings under 37 C.F.R. §1.83(a) is appropriate.

As stated previously, the drawings have been objected to under 37 C.F.R. §1.83(a) as failing to show every feature of the invention specified in the claims. More particularly, the Office objects that the multi-phased composite drug delivery unit of claim 60 must be shown in the figures, or the feature cancelled from the claim. In response, applicants draw the Office's attention to the amendment to Figure 2 provided herewith. As can be seen, the multi-phase carrier material (14) is shown in Figure 2 as including two different materials, one depicted by the broken diagonal lines, and the other by the unmarked background of the drug delivery unit (10). As described in detail in the specification at page 40, lines 2-19, the carrier material can be a single material (e.g., see Figure 1, and see also Figure 2 where both the broken lines and the unmarked background are the same material), or alternatively there can be multiple (e.g., two) carrier materials (e.g., see Figure 2, where the broken lines and the unmarked background comprise different carrier materials). The term "multi-phase" is used by those skilled in the pharmaceutical arts to refer to a system where two different carrier materials are used in a single controlled release dosage form. Such systems can be formed using a single type of polymer (e.g., a biodegradable polyester) where two different molecular weight species of the polymer are employed, or where two different polymers are used (e.g., two different biodegradable polymers having differing dissolution characteristics to provide

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one or more zones that will dissolve faster than other zones. See applicants' specification at page 30, lines 28-33.

Rejection under 35 U.S.C. §103 over Manning

Claims 1, 26-29, 48-49, 53, 63-71 and 75-82 remain rejected under 35 U.S.C. §103(a) as unpatentable over Manning for the reasons of record. Applicants continue to traverse this rejection.

As a matter of form, claims 1, 27, 48, 49, 53, 63-65, 69, and 79 have been cancelled, making moot their rejection.

Applicants' amended independent claim 71 recites a method whereby a drug delivery unit is inserted directly into the round window niche and positioned either partially or completely within the round window niche, wherein the unit is configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand. Manning does not teach or disclose delivery of a drug unit directly into the round window niche configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand.

The Office Action fails to show that all of the claim limitations are taught or suggested by the prior art. Accordingly, the Office Action fails to establish a prima facie obviousness of the claimed invention. MPEP § 2143.03.

Rejection under 35 U.S.C. §103 over Manning in view of Peterson

Claims 50-52, 54-59 and 72-74 stand rejected under 35 U.S.C. §103(a) as unpatentable over Manning in view of Peterson for the reasons of record. Applicants traverse the rejection.

As a matter of form, claims 50-52 have been cancelled, making moot their rejection.

Applicants' amended independent claim 71 recites a method whereby a drug delivery unit is inserted directly into the round window niche and positioned either partially or completely within the round window niche, wherein the unit is configured as

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a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand. Manning does not teach or disclose delivery of a drug unit directly into the round window niche configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand. Likewise, Peterson teach or disclose delivery of a drug unit directly into the round window niche configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand. Furthermore, none of the cited references teaches or suggests the modification of either Manning or Peterson to incorporate delivery of a drug unit directly into the round window niche configured as a pellet, disk, tablet, plate, sphere, cube, cylindrical unit, or strand.

Accordingly, the combination of references cited in the Office Action fails to show that all of the claim limitations are taught or suggested by the prior art. Thus, the Office Action fails to establish a prima facie obviousness of the claimed invention. MPEP § 2143.03.

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CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4914.

The appropriate fee is attached or authorized. If the Commissioner determines that an additional fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1953.

Respectfully submitted,



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